APR 19 2006

K060731

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLVE® Modular Radial Head.

Submitted By:	Wright Medical Technology, Inc.
Date:	March 17, 2006
Contact Person:	Wesley L. Reed Regulatory Affairs Specialist II
Proprietary Name:	**EVOLVE® Modular Radial Head**
Common Name:	Modular Radial Head
Classification Name and Reference:	21 CFR 888.3170 Elbow joint radial (hemi elbow) polymer prosthesis – Class II
Device Product Code and Panel Code:	Orthpedics/87/KWI

DEVICE INFORMATION

A. INTENDED USE

Use of the Modular Radial Head Implant may be considered for :

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  a. joint destruction and/or subluxation visible on x-ray; and/or
  b. resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

B. DEVICE DESCRIPTION

The EVOLVE® Modular Radial Head Implant System is being extended to include additional size stems and heads. The design features of these additional sizes are identical to the previously submitted and cleared stems and heads under 510(k): K991915- EVOLVE® Modular Radial Head.

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011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, type of interface, operating principles, shelf life, and design features of the EVOLVE® Radial Head Implant are substantially equivalent to the head component covered under the EVOLVE® Modular Radial Head 510(k): K991915. Additionally, the safety and effectiveness of the EVOLVE® Radial Head Implant is adequately supported by the substantial equivalent information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2006

Wright Medical Technologies, Inc.
c/o Mr. Wesley L. Reed
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K060731
Trade/Device Name: EVOLVE Modular Radial Head
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: March 17, 2006
Received: March 20, 2006

Dear Mr. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060731

Device Name: EVOLVE® Modular Radial Head

Indications For Use:

Use of the Modular Radial Head Implant may be considered for :

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
  a. joint destruction and/or subluxation visible on x-ray; and/or
  b. resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorati...
and Neurological Devices

510(k) Number K060731